AMERICAN
ASSOCIATION
OF BLOOD BANKS

December 2, 1999

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Docket Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852-1448

Docket No. 98N-0673

Re: Direct Final Rule Revisions to the Requirements Applicable to Blood, Blood Components, and SourcePlasma

To Whom it May Concern:

The AABB is the professional association for approximately 2200 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8500 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety of the nation's blood supply.

The FDA is amending the biologics regulations to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. The AABB applauds this action and in general agrees that actions proposed in the direct final rule are appropriate. There are some specific provisions that do need attention. Our comments follow:

Section 606.3 **(j)** proposes a new definition of compatibility testing by removing the reference to serological tests and making the definition more general to apply to all tests performed to establish the matching of a donor's blood or blood components with that of a potential recipient. This change is intended to provide for current practices used in compatibility testing, such as the electronic crossmatch and the immediate spin cross

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match. The AABB supports this intent as it would eliminate the need for blood establishments to file for a variance to compatibility testing under 640.120. However, using the term "tests performed" still seems to imply serological testing. **It would be less ambiguous if another term such as "procedures" performed were used in the definition.**

Section 606.151 (c) also uses the word "testing" which further reinforces the idea of serological testing being required. The explanation of the change indicates that this change is intended to accommodate the use of such procedures as immediate spin crossmatch and an electronic crossmatch. **We suggest "Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum type"**

Section 606.151 (b) requires the use of fresh recipient serum samples less than 3-days old for all pretranfusion testing if the recipient has been pregnant or transfused within the previous 3 months. The use of plasma samples is not uncommon for these tests, and is specifically permitted by FDA in the December 14, 1984 Memorandum on Equivalent Methods for Compatibility Testing. The AABB *Standards for Blood Banks and Transfusion Services* has allowed use of either plasma or serum since **198** 1. **We request that this section be changed to permit the use of plasma or serum.** This would bring the section into agreement with recognized practice.

Section 640.3 (c) (1) and 640.63 (c) (11) are amended to read a history of hepatitis "after the age of eleven". The definition of "after the age of eleven" is not clear. It could be interpreted either as after the eleventh birthday, or when one is no longer eleven, which would be after the twelfth birthday. **It would be more precise and easier to interpret if it said after the eleventh birthday or after the twelfth birthday.**

Section 640.5 (c) refers to tests for "the Rh Variant D"". Due to the changes in anti-D reagents over the years, the original use of the term D" is no longer applicable. The term D" is now considered obsolete and has been replaced by the term **"weak** D". **We request that "weak D" be substituted for "Rh Variant D^{u}".** Note that weak expression of D is the term used in the explanation of the change provided in the Highlights of the Direct Final Rule section.

Section 640.24 **(b)** is amended by changing the time period for separation of platelet concentrates to read "within the time period specified in the directions for use for the specific device." Similar changes are made to **Sections 640.34 (a) through (d) and (e)(l)** for the timeframe for storage of plasma and **Section** 640.54 **(a)** (2) for the freezing of plasma. While we support the purpose of the amendment, which is to permit more flexibility by permitting different timeframes, the AABB is not aware that the manufacturers of blood collection devices specify this information. **If this change is to be instituted, then manufacturers must be required to include such information in their device labeling. Alternately, the FDA could reference the *AABB Standards for Blood Banks and Transfusion Services* where these details are specified.**

Section 640.34 **(b)** also states that the plasma shall be frozen solid within the time frame specified in the directions for use for the specific device. The term "frozen solid" has not been in use for several years. **We request that "frozen solid" be changed to read "separated and placed in the freezer".** This would be consistent with the wording in Standard D4.100 of the AABB *Standards for Blood Bank and Transfusion Services.*

Section 640.25 (b) and 640.56 **(a)** are discussed in the Highlights of the Direct Final Rule, where it states that these sections are amended to require testing for quality control only in those months in which blood products are prepared for use. We support this concept; however, the exact wording changes do not appear in the List of Subjects under Part **640. We request that the exact wording for these two sections be published.**

Section 640.62 states that a licensed physician must be available to attend the donor within 15 minutes when a pheresis procedure is being performed. We request that this be reconsidered. With the pheresis equipment in use today, there is much less likelihood of a severe adverse reaction, and should one occur, access to trained emergency services such as the ability to call 911 is readily available. **We suggest that the wording be changed to "emergency medical services are available within 15 minutes."**

We would also like to request consideration of one additional change that is not discussed in the Direct Final Rule. **Section** *640.4* **(i)** *Storage* currently states that "Immediately after collection, unless the blood is to be used as a source for Platelets, it shall be placed in storage at a temperature between 1 and 6C unless it must be transported from the donor clinic to the processing laboratory. It is now possible to prepare other components, such as buffy coats for Source Leukocytes, which require that whole blood remain at room temperature. The *AABB Standards for Blood Bank-s and Transfusion Services. I 9th Ed,* has addressed this issue in Section Cl .600. Standard Cl .610 states "After collection, blood shall be cooled toward 1-6C, except if it is to be used for room temperature component preparation, in which case it should not be cooled below 20 C. Standard Cl .620 addresses the transport issue and states "If blood shall be transported from the collection site to the component processing laboratory, it shall be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a reange of l-6 C until it arrives at the processing laboratory."
We request consideration of this language in the Direct Final Rule.

The AABB is pleased to have this opportunity to comment on the Direct Final Rule. If you have any questions about these comments, please contact Kay Gregory, Director Regulatory Affairs at 301-2 15-6522 or kayg@aabb.org.

Yours truly,

Paul Ness, MD
President